UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

APR | 8 1997

Wendy Urtel Metrex Research Corporation 1717 West Collins Avenue Orange, CA 92867

Subject Cavacıde

EPA Registration No 46781-6 Notification Per PR-Notice 95-2

Dear Ms Urtel

This will acknowledge receipt of your notification, for an additional brand name (MetriGuard) submitted under the provisions of FIFRA section 3 (c) 9 Based on a review of the submitted material, the following comments apply

The application is acceptable and the notification has been made a part of the records for this file

Sincerely,

Wanda Y Mitchell Notification Coordinator Antimicrobial Program Branch Antimicrobial Division (7505W)

CONCURRENCES								
SYMBOL > 7505W								
SURNAME Mitchell	*****			******************			*************	
DATE 4-18-97								
DATE 4-18-97								

EPA Form 1320-1A (1/90)

Printed on Recycled Paper

OFFICIAL FILE COPY *U S GPO 1994-522-503/82085

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Approval	expires 05-31-98	2/5
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	United States	-		Registra	tion	OPP Identifier Number
EPA	Environmental Protection			☐ Amendm	ent	
·	Washington, DC 20					
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1, Company/Prod	uct Number	1,25%	 EPA Product Ma arion_Johnson	nager	3. 1	Proposed Classification
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	Corporation/Cavicide	3				
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Metrex Research 1717 West Coll:		_ ********	and labeling to:			
	2867		EPA Reg. No			
	if this is a new address		Product Name			
		Sec	tion - II			
Amendment -	Explain below.			rinted labels in	response	to
			Agency	letter dated		
Resubmission	in response to Agency letter dat	ed	[o* Application.		
X Notification - E	Explain below,		Other -	Explain below.		(1977년 - 1971년 - 1977년 - 1977년 - 1977년 - 1977
Explanation: Use	additional page(s) if necessary.	For Section I	and Section II.)			
This submission	n is a NOTIFICATION OF A	N ALTERNAT	E BRAND NAME for	r the produ	ct Cavi	cide,
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See additional	page.					
	* ,					
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Name	Complete items directly below for	Title	i individual to be con			No. (Include Area Code)
Wendy A. Urtel	1	-	Affaire Emogia	1	-	•
wendy A. Ofter		ication	Affairs Specia	1156 17	14 <u>-516-</u>	6. Date Application
I certify that the statements I have made on this form			all attachments there	eto are true,	1	Resolved
3	d complete. I acknowledge that			statement		
	nishable by fine or imprisonment		applicable law.	- · · · · · · · · · · · · · · · · · · ·	1111	(Stamped)
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Wendy A. Mirtel		March 6	1007	_		1

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APPLICATION FOR PESTICIDE NOTIFICATION OF ALTERNATE BRAND NAME

Product name: Cavicide, EPA Reg. No. 46781-6
Alternate Brand Name: MetriGuard

Section II - Additional Page

This notification is consistent with the provisions of PR Notice 95-2 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the Confidential Statement of Formula of this product. I understand that it is a violation of 18 U.S.C. Section 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 95-2 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

METRIGUARD

SURFACE DISINFECTANT/DECONTAMINANT CLEANER

Product No.: MX-7500

Non-Staining
Non-Corrosive
Non-trritating
No Dilution Required
Ready to Use
No Toxic Fumes

EPA Reg. No. 46781-6 EPA Est. No. 46781-CO-1

Net Contents: Dne Gallon (128 FL, DZ./3.8 L) Surface Cleaner/Disinfectant
Ultrasonic Solution
Soaking Solution
Presoak Solution
Bactericidal
Virucidal*
Fungicidal
Tuberculocidal**

For Professional Use Contains Blodegradable Detergent

ACTIVE INGREDIENTS
Dissobutylphenoxyethoxyethyl

dimethyl benzyl ammonium chloride 0 25% isopropanol 15 30% inert ingredients 84 45% Total 100 00%

CAUTION. KEEP OUT OF REACH OF CHILDREN

PRECAUTIONARY STATEMENTS Harmful to Humans and Domestic Animals Avoid contamination of food May cause the first Avoid direct contact with eyes in case of direct eye contact mimediately flush eyes with piech / of N 3 or for at east 15 minutes. If inflation persists seek medical attention

METRIGUARD effectively kills HIV on precleaned environmental surfaces/objects previously soiled with blood/body fluids in healthcare settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood/body fluids and in which the surfaces/objects can be associated with the potential for transmission of Human Immunodeficiency Virus type-1 (HIV 1)

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV 1 (HUMAN IMMUNODEF)CIENCY VIRUS) OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUID

PERSONAL PROTECTION Wear appropriate barrier protection such as latex gloves gowns masks or eye coverings CLEANING PROCEDURE Blood and other bodily fluids must be thoroughly cleaned from surfaces and objects before disinfection with Metricipans

CONTACT TIME While the HIV 1 virus is inactivated in 2 minutes use the recommended contact time for the disinfection of other organisms listed on this label

INFECTIOUS MATERIALS DISPOSAL Cleaning materials used that may contain blood or other bodily fluids should be autoclayed and/or disposed of in accordance with local regulations for infectious materials disposal

***This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that
(1) is introduced directly into the human body either into or in contact with the bloodstream or normally sterile
areas of the body or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier
or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical
or semi-critical medical devices prior to sterilization/high level disinfection.

For product information please contact our Customer Service Department at 1 800 841 1428

21 6

STORAGE AND DISPOSAL.

STORAGE Store in a cool place

PESTICIDE DISPOSAL Dilute with water Dispose of in ordinary sanitary sewer

CONTAINER DISPOSAL Triple rinse Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill or incineration or if allowed by state and local authorities by burning if burned keep out of smoke

Manufactured by:



10270 S Dransfeldt Rd Parker CO 80134

7010 3

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DIRECTIONS FOR USE:

It is a violation of U.S. Federal law to use this product in a manner inconsistent with its labeling.

DESCRIPTION:

METRIGUARD is a ready-to-use, highly effective cleaner and disinfectant for use on the surfaces of inanimate objects. It is useful in hospital operating rooms, isolation areas, and other critical care areas where the control of cross contamination is important. METRIGUARD will clean and disinfect, when used as directed, such items as: anesthesia machines and respiratory therapy equipment surfaces, operating room tables and lights, and other inanimate surfaces, including those made of plastics (such as: polycarbonate, polyvinylchloride, polypropylene and polystyrene), non-porous vinyl and upholstery, stainless steel, painted surfaces. Plexiglas®, glass, and other hard non-porous surfaces.

EFFECTIVE AGAINST: Staphylococcus aureus, Pseudomonas aeruginosa, Salmonella choleraesuis, Mycobacterium tuberculosis var: bovis (BCG)**, Methicillin Resistant Staphylococcus aureus (MRSA), Vancomycin Resistant Enterococcus faecalis (VRE), Trichophyton mentagrophytes, Herpes simplex virus types 1 and 2, Human Immunodeficiency Virus (HIV-1)*, Poliovirus types 1 and 2, and Coxsackievirus. (*On inanimate surfaces.) (**In 10 minutes at room temperature - 20°C.)

APPLICATIONS:

FOR USE AS AN INSTRUMENT ULTRASONIC CLEANING SOLUTION:

Thoroughly pre-rinse instruments under running water to remove visible gross debris. Using 1 ounce **MetraGuaso** per liter of water in ultrasonic unit, immerse instruments into mixed solution and activate ultrasonic unit for 5 minutes or longer if necessary. Remove instruments and rinse thoroughly. Change solution as needed. Follow with appropriate disinfection process. (**Critical and semi-critical devices must be followed by appropriate terminal sterilization/high-level disinfection process.**)

FOR USE AS A MANUAL INSTRUMENT CLEANER:

Thoroughly pre-rinse dirty instruments under running tap water to remove visible gross debris. Place pre-rinsed instruments into a solution of 1 ounce METRICUARD per liter of water. Scrub instruments using a stiff bristle brush until visibly clean. (Instruments should be submerged as scrubbed.) Rinse instruments thoroughly. Change solution as needed. Follow with appropriate disinfection process. (Critical and semi-critical devices must be followed by appropriate terminal sterilization/high-level disinfection process.)

FOR DISINFECTION OF NON-CRITICAL PRECLEANED INSTRUMENTS:

Instruments must be thoroughly precleaned to remove excess organic debris, rinsed and then rough dried. (Clean and rinse lumens of hollow instruments before filling with solution or before immersion.) Using either a soaking tray or ultrasonic unit, immerse instruments into undiluted MetruGuard solution and allow to remain submerged for 2 minutes. For tuberculocidal activity, allow 10 minutes at room temperature (69° f/20°C). Remove and rinse or wipe dry prior to use. Change solution dally or more often as needed if the solution becomes diluted or visibly soiled. (Critical and semi-critical devices must be followed by appropriate terminal sterilization/high-level disinfection process.)

SURFACES: (Where appropriate, follow Universal Precautions.)

FOR PRECLEANING MEDICAL EQUIPMENT AND OTHER SURFACES PRIOR TO DISINFECTION: Apply Metricular directly to precleaned surface. Allow to remain wet for 30 seconds. Wipe surface clean using a paper or cloth towel or rinse surface and either wipe dry or allow to air dry. Discard dirty towel.

FOR DISINFECTING PRECLEANED MEDICAL EQUIPMENT AND SURFACES:
Apply Metricuard directly to precleaned surface, thoroughly wetting area to be disinfected.
Allow surface to remain wet for 2 minutes at room temperature (69°F / 20°C).

**(For Tuberculocidal Activity: Allow 10 minutes.) Follow by wiping surface using a clean paper or cloth towel; or rinse and either allow surface to air dry or wipe rinsed surface dry using a clean paper or cloth towel. Discard towel.

INSTRUMENTS: (Where appropriate, follow Universal Precautions.)
FOR USE AS AN IMMERSION PRECLEANING INSTRUMENT DECONTAMINANT
SOLUTION: Fill appropriate size container with a sufficient amount of undiluted
METRIGUARD so as to allow for complete submersion of instruments. Place instruments
into METRIGUARD solution, cover and allow to soak for 10 minutes. Remove and rinse.
Follow with appropriate cleaning and disinfection process. Change solution as needed
when the solution becomes diluted or visibly solled. (Critical and semi-critical devices
must be followed by appropriate terminal sterilization/high-level disinfection
process.)

FOR USE AS AN INSTRUMENT PRECLEAN DECONTAMINATION SPRAY:
Place instruments into a sultable container. Thoroughly spray Metricuard solution
onto instruments so as to thoroughly drench all surfaces. Cover instruments and
transport to appropriate cleaning area. Rinse instruments, follow with appropriate
cleaning and disinfection process. (Critical and semi-critical devices must be followed
by appropriate terminal sterilization/high-level disinfection process.)

4/18/97

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

APR 1 8 1997

Wendy Urtel Metrex Research Corporation 1717 West Collins Avenue Orange, CA 92867

Subject

Cavacide EPA Registration No 46781-6

Notification Per PR-Notice 95-2

Dear Ms Urtel.

This will acknowledge receipt of your notification, for an additional brand name (Kerr Cavacide) submitted under the provisions of FIFRA section 3 (c) 9 Based on a review of the submitted material, the following comments apply

The application is acceptable and the notification has been made a part of the records for this file

Sincerely,

Wanda Y Mitchell Notification Coordinator Antimicrobial Program Branch Antimicrobial Division (7505W)

CONCURRENCES									
SYMBOL	7505W		********						
SURNAME	Mitchell								
DATE)	4-18-97								

EPA Form 1320-1A (1/90)

Printed on Recycled Paper

OFFICIAL FILE COPY U.S. GPO 1994-522-503/82085

3/10/97 2:07 PM Plase read instructions	on reverse before completing	g form.	Form Appro	ved. OMB	No. 2070-		s 05-31-9
EPA	United States Environmental Protection Washington, DC 20			_ A	Registration Imendment Other	1	Number
	Appli	cation for	Pesticide -s	ection I	 		
1. Company/Product I			2. EPA Product			3. Proposed Classif	ication
46781 / 46781-6		· <u>N</u>	Marion Johnson				
4. Company/Product (PM#			🗴 None 🔲 Re	estricted
	rporation/Cavicide		S1				
Metrex Research Co 1717 West Collins		··· ·· ··		ny produc		with FIFRA Section or identical in compos	ition
Orange, CA 9286			EPA Reg. N	0			· · · · · · · · · · · · · · · · · · ·
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* Certification must be submitted	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per contain	· 🗀 Þ	ilass aper Other (Specify)	
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Label	Container	-1. 0/25(5)			☐ On La		product
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		Sei	ction - IV				
1. Contact Point (Com	lete items directly below for			contacted.	if necessar	y, to process this appl	ication.)
Name		· Title				phone No. (Include Are	
Wendy A. Urtel		Regulator	y Affairs Spec	ialist		516-7425	ŕ
I certify that the accurate and c	statements I have made or omplete. I acknowledge that	fication this form and any knowing	d all attachments the	hereto are	true,	6. Date Applie Received	
may be punisha	ble by fine or imprisonment	or both unde	r applicable law.			(Stamped))
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4 Typed Name	· · · · · · · · · · · · · · · · · · ·	5 Date				, , ,	

March 7, 1997

Wendy A. Urtel

-3/5

APPLICATION FOR PESTICIDE NOTIFICATION OF ALTERNATE BRAND NAME

Product name: Cavicide, EPA Reg. No. 46781-6 Alternate Brand Name: Kerr Cavicide

Section II - Additional Page

This notification is consistent with the provisions of PR Notice 95-2 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the Confidential Statement of Formula of this product. I understand that it is a violation of 18 U.S.C. Section 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 95-2 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

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EFFECTIVE AGAINST: • Staphylococcus aureus • Pseudomonas aeruginosa • Salmonella choleraesuls • Mycobacterium tuberculosis var: bovis (BCG)** • Methicillin Resistant Staphylococcus aureus (MRSA) • Vancomycin Resistant Enterococcus faecalis (VRE) • Trichophyton mentagrophytes • Herpes simplex virus types 1 and 2° • Human Immunodeficiency Virus (HIV-1)° • Policylius types 1 and 2° • Coxsackievirus', ("On inanimate surfaces.) ("In 10 minutes at room temperature - 20°C.)

DIRECTIONS FOR USE:

it is a violation of U.S. Federal law to use this product in a manner inconsistent with its labeling.

DESCRIPTION: Kerr Cavicide is a ready to use, highly effective cleaner and disinfectant for use on the surfaces of inanimate objects. Useful in hospital operating rooms, isolation areas, necreatal units, and other critical care areas where environmental control of cross contamination. is important. Kerr Cavidade will clean and disinfect, when used as directed, such items as: infant incubators and bassinets, ansihesia machines and respiratory therapy equipment surfaces, operating morn tables and lights, and other inanimate surfaces, including those made of plastics (such as; polycarbonate, polycarbonate, polypropylene and polystyrene), non-porcus vinyl and uphoistery, stainless steel, painted surfaces, Plexiglas, glass, and other hard non-porcus surfaces.

APPLICATIONS:

SURFACES: (Where appropriate, follow Universal Precautions.)

For precleaning medical equipment and other surfaces prior to disinfection:

Apply directly to surface. Allow to remain wet for 30 seconds. Wipe surface clean using a paper or cloth towel or rinse surface and either wipe dry or allow to air dry. Discard dry towel.

For disinfecting medical equipment and surfaces:

For disinfecting medical equipment and surfaces:

Apply Kerr Cavicide directly to precisaned surface, thoroughly wetting area to be disinfected. Allow surface to remain wet for 2 minutes at room temperature (69° F/20° C). "(For Tubeccalocidel Activity: allow 10 minutes.) Follow by wiping surface using a clean paper or cloth towel; or risse and either allow surface to air dry or wipe insed surface dry using a clean paper or cloth towel. Discard towel.

KERR CAVICIDE EFFECTIVELY KILLS HIV ON PRECLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS IN HEALTHCARE SETTINGS OF OTHER SETTINGS IN WHICH THERE IS AN EXPECTED LIKELIHOCO OF SOILING OF INANIMATE SURFACES/OBJECTS WITH BLOOD/BODY FLUIDS, AND IN WHICH THE SURFACES/OBJECTS CAN BE ASSOCIATED WITH THE POTENTIAL FOR TRANSMISSION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE-1 (HIV-1).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (HUMAN IMMUNODEFICIENCY VIRUS) OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUID: *Personal Protection:* Wear appropriate barrier protection such as leftly gloves, gowns, meaks or eye coverings. *Cleaning Protection Times to the disinfection winds. *Cleaning from times to the surfaces and objects before disinfection winds. *Cleaning from times to the surfaces and objects before disinfection winds. *Cleaning foot times to the surfaces and objects before disinfection winds. *Cleaning foot times to the surfaces and objects before disinfection of other organisms letted on this label. *Infectious Materials Disposal: Cleaning materials used that may contain blood or other bodily fluids should be autoclaved and/or disposed of in accordance with local regulations for infactious materials disposed. materials disposal.



SURFACE DISINFECTANT / DECONTAMINANT CLEANER

BACTERICIDAL • VIRUCIDAL* • FUNGICIDAL • TUBERCULOCIDAL** READY TO USE - CONTAINS BIODEGRADABLE DETERGENT

ACTIVE INGREDIENTS:

Diisobutylphenoxyethoxyethyl dimethyl benzyl ammonium chloride.........0.25%

KEEP OUT OF REACH OF CHILDREN CAUTION

PRECAUTIONARY STATEMENTS: HARMFUL TO HUMANS AND DOMESTIC ANNUALS, AVOID CONTAMINATION OF FOOD, MAY CAUSE EYE IRRITATION, AVOID DIRECT CONTACT WITH EYES, IN CASE OF DIRECT EYE CONTACT, IMMEDIATELY FLUSH EYES WITH ; PLENTY OF WATER FOR AT LEAST 15 MINUTES, IF PRRITATION PERSISTS, SEEK VEDICAL ATTENTION.

EPA REG NO.: 46781-6

EPA EST NO.: 45781-CO-1

Reorder No: 06-0104

Net Contents 1 U.S. Gallon / 3.785 Liters (Net Weight 8.22 Lbs / 3.73 kg)

41.1

KERR CAVICIDE 1 GAL 3/10/97 11:59 AM Page 1 (2.1)

INSTRUMENTS: (Where appropriate, follow Universal Precautions.)

For use as an immersion precleaning instrument decontaminant solution:

Fill appropriate size container with a sufficient amount of undiffuted Kerri Cavicide so as to allow for complete submersion of instruments. Place instruments into Kerr Cavicide solution, cover and allow to soak for 10 minutes. Remove and rinse. Follow with appropriate cleaning and distritection process. Change solution as needed when the solution becomes diluted or visibly solied. (Critical and semi-critical devices must be toBowed by appropriate terminal sterilization/high-level disintection process.)
For use as an instrument preciean decontamination spray:

Place instruments into a suitable container. Thoroughly spray Kerr Cavicide solution onto instruments so as to thoroughly drench all surfaces. Cover instruments and transport to appropriate cleaning area. Rinse instruments, follow with appropriate cleaning and disinfection process, (Critical and semi-critical devices must be followed by sepropriste terminal sterilization/high-level disinfection process.)

For use as an instrument uffrasonic cleaning solution:

Thoroughly pre-rinse instruments under running water to remove visible gross debris. Using 1 ounce Kerr Cavicide per litter of water in ultrasonic unit, immerse instruments into mixed solution and activate unit for 5 minutes or longer if necessary. Remove instruments and rinse thoroughly. Change solution as needed. Follow with appropriate disinfection process. (Critical and semi-critical devices must be followed by appropriate terminal sterilization/high-level disinfection process.)

For use as a manual instrument cleaner:

Thoroughly pre-rinse dirty instruments under running tap water to remove visible gross debris. Place pre-rinsed instruments into a solution of 1 ounce Kert Cavicide per lifer of water. Scrub instruments using a stiff bristle brush until visibly clean, (Instruments should be submerged as scrubbed.) Rinse instruments thoroughly. Change solution as needed. Follow with appropriate disinfection process. (Critical and semi-critical devices must be followed by appropriate terminal startlization/high-level disintection process.)

For disintection of NON-CRITICAL precisaned instruments:

Instruments must be thoroughly precleaned to remove excess organic debris, rinsed and then rough dried. (Clean and rinse timens of hollow instruments before filling with solution or before immersion.) Using either a soaking tray or ultrasonic unit, immerse instruments into undifuted Kerr Cavicide solution and allow to remain submerged for 2 minutes. For tuberculocidal activity, allow 10 minutes at room temperature (69°F/20°C). Remove and thise of wipe dry prior to use. Change solution daily or more often as needed if the solution becomes diluted or visibly solled. (Critical and semi-critical devices must be followed by appropriate terminal sterilization/hab-tevel disinfection process.)

"This product is not to be used as a terminal sterilizativity into the

human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to aterilization/high-level disinfection.

STORAGE AND DISPOSAL:

STORAGE: Store in a cool place, PESTICIDE DISPOSAL: Dilute with water. Dispose of in ordinary sanitary sewer, CONTAINER DISPOSAL: Triple rinse. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, keep out of smoke.

For product information, please contact our technical service department at 1-800-841-1428 (TOLL FREE).

Destributed By:

Metrex Research Corp. 10270 S. Dransfeldt Rd. Parker, CO 80134

6350-2